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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172, 173, and 184

Foods and Drugs; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations that incorporate by reference analytical methods in the ''Food Chemicals Codex'' 3d edition, by updating these references to the 4th edition. Additionally, the agency is concomitantly updating the incorporation by reference for specifications in six regulations that incorporate by reference specification monographs in the ''Food Chemicals Codex'' 3d edition, by updating these references to the 4th edition. This action is being taken to meet the requirements for incorporation by reference set forth in 1 CFR part 51.

DATES: The regulation is effective (*insert date of publication in the* **Federal Register**). The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications listed in §§ 172.345(b), 172.665(d)(2), 172.723(b)(3), 173.310(c), 184.1007(b)(1), (b)(6), and (b)(7), 184.1257(b) and (b)(1), 184.1259(b)(3), 184.1282(b), 184.1293(b), 184.1530(b), 184.1699(b), 184.1979(b)(1) and (b)(2), 184.1979a(b)(1) and (b)(2), 184.1979b(b)(1) and (b)(2), and 184.1979c(b)(1) and (b)(2) (21 CFR 172.345(b), 172.665(d)(2), 172.723(b)(3), 173.310(c), 184.1007(b)(1), (b)(6), and (b)(7), 184.1257(b) and (b)(1), 184.1259(b)(3), 184.1282(b), 184.1293(b), 184.1530(b), 184.1699(b), 184.1979(b)(1) and (b)(2), 184.1979a(b)(1) and (b)(2), 184.1979b(b)(1) and (b)(2), and 184.1979c(b)(1) and (b)(2)), effective (*insert date of publication in the* **Federal Register**).

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in parts 172, 173, and 184 (21 CFR parts 172, 173, and 184) that incorporate by reference analytical methods in the ''Food Chemicals Codex'' 3d edition, by revising §§ 172.665, 172.723, 173.310, 184.1007, 184.1257, 184.1259, 184.1979, 184.1979a, 184.1979b, and 184.1979c to incorporate identical methods in the 4th edition of the ''Food Chemicals Codex.'' Additionally, the agency is amending regulations in parts 172 and 184 that incorporate by reference specification monographs in the 3d edition of the ''Food Chemicals Codex,'' by revising §§ 172.345, 184.1257, 184.1282, 184.1293, 184.1530, and 184.1699 to incorporate identical specification monographs in the 4th edition. 1 CFR part 51 requires filing and updating of material that has been incorporated by reference in the CFR.

The agency is also taking this opportunity to amend the previous regulations to: (1) Reflect a change in the address of the National Academy Press and to add its Internet address; (2) reflect a change in the name and address of the Association of Official Analytical Chemists International (AOAC), as published as a technical amendment in the **Federal Register** of March 24, 1998 (63 FR 14035), which updated this reference in 21 CFR parts 101 through 169; and (3) revise sections in part 184.

FDA has reviewed the food ingredient regulations that incorporate by reference material in the ''Food Chemicals Codex.'' The edition of the ''Food Chemicals Codex'' cited when many of these regulations were established (3d edition) has been superseded by a subsequent edition (4th edition). The agency has compared specification monographs and methods in the 3d and 4th editions and found that no substantive changes have been made to the material incorporated by reference into the regulations amended in this document. The agency notes that in the 3d edition, reagents are often cited as test solutions (TS), without giving the strength of the reagent in the specification monograph or the analytical method. This requires the analyst to refer to the section

on TS in the back of the volume. In ''Food Chemical Codex'' 4th edition, the TS reagent strengths are also given in the individual specification monographs and analytical methods. This change is only editorial in nature.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely updating incorporations by reference that involve nonsubstantive changes.

List of Subjects

21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

21 CFR Part 173

Food additives, Incorporation by reference.

21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR parts 172, 173, and 184 are amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.345 is amended by revising paragraph (b) to read as follows:

§ 172.345 Folic acid (folacin).

* * * * *

(b) Folic acid meets the specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 157–158, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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3. Section 172.665 is amended by revising paragraph (d)(2) to read as follows:

§ 172.665 Gellan gum.

* * * * *

(d) * * *

(2) Residual isopropyl alcohol (IPA) not to exceed 0.075 percent as determined by the procedure described in the Xanthan Gum monograph, the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 437–438, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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4. Section 172.723 is amended by revising paragraph (b)(3) to read as follows:

§ 172.723 Epoxidized soybean oil.

* * * * *

(b) * * *

(3) The heavy metals (as Pb) content cannot be more than 10 parts per million, as determined by the ''Heavy Metals Test,'' of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, Method II (with a 2-gram sample and 20 microgram of lead ion in the control), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

5. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

6. Section 173.310 is amended in the table in paragraph (c) in the entry for ''Sodium carboxymethylcellulose'' to read as follows:

§ 173.310 Boiler water additives.

* * * * *

(c) * * *

Substances	Limitations
* * * *	* * *
Sodium carboxymethylcellulose	Contains not less than 95 percent sodium carboxymethylcellulose on a dry-weight basis, with maximum substitution of 0.9 carboxymethylcellulose groups per anhydroglucose unit, and with a minimum viscosity of 15 centipoises for 2 percent by weight aqueous solution at 25 °C; by the method prescribed in the "Food Chemicals Codex," 4th ed. (1996), pp. 744–745, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address "http://www.nap.edu"), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.
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PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

7. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

8. Section 184.1007 is amended by revising paragraphs (b)(1), (b)(6), and (b)(7) to read as follows:

§ 184.1007 Aconitic acid.

* * * * *

(b) * * *

(1) *Assay.* Not less than 98.0 percent of $C_3H_3(COOH)_3$, using the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 102–103, test for citric acid, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, and a molecular weight of 174.11. Copies of the material incorporated by reference are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug

Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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(6) *Readily carbonizable substances.* Passes the test for citric acid of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 102–103, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(7) *Residue on ignition.* Not more than 0.1 percent as determined by the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 102–103, test for citric acid, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

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9. Section 184.1257 is amended by revising the introductory text of paragraph (b) and by revising paragraph (b)(1) to read as follows:

§ 184.1257 Clove and its derivatives.

* * * * *

(b) Clove bud oil, clove leaf oil, clove stem oil, and eugenol meet the specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 104–105, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. As determined by analytical methods in the ''Food Chemicals Codex,'' clove oleoresin or other natural

extractives (other than clove oils) meet the ''Food Chemicals Codex'' specifications for clove (clove bud) oil and the following modifications:

(1) The assay for phenols, as eugenol, by the ''Food Chemicals Codex'' test, 4th ed. (pp. 104–105), or the volatile oils content by the ''Food Chemicals Codex'' test, 4th ed. (pp. 104–105) should conform to the representation of the vendor;

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10. Section 184.1259 is amended by revising paragraph (b)(3) to read as follows:

§ 184.1259 Cocoa butter substitute.

* * * * *

(b) * * *

(3) Heavy metals (as lead), not more than 10 milligrams per kilogram, as determined by the Heavy Metals Test of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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11. Section 184.1282 is amended by revising paragraph (b) to read as follows:

§ 184.1282 Dill and its derivatives.

* * * * * *

(b) Dill oils meet the description and specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 122–123, which is incorporated by reference in accordance with 5 U.S.C. 552(a)

and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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12. Section 184.1293 is amended by revising paragraph (b) to read as follows:

§ 184.1293 Ethyl alcohol.

* * * * *

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), p. 136, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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13. Section 184.1530 is amended by revising paragraph (b) to read as follows:

§ 184.1530 Niacin.

* * * * *

(b) The ingredient meets the specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), p. 264, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center

for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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14. Section 184.1699 is amended by revising paragraph (b) to read as follows:

§ 184.1699 Oil of rue.

* * * * *

(b) Oil of rue meets the specifications of the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 342–343, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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15. Section 184.1979 is amended by revising the introductory text of paragraph (b)(1), by revising paragraph (b)(2), and by removing footnote numbers ''1'' and ''2'' to read as follows:

§ 184.1979 Whey.

* * * * *

(b) * * *

(1) The analysis of whey, concentrated whey, and dry (dried) whey, on a dry product basis, based on analytical methods in the referenced sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through

(b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent) as determined by the method described in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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16. Section 184.1979a is amended by revising the introductory text of paragraph (b)(1), by revising paragraph (b)(2), and by removing footnote numbers ''1'' and ''2'' to read as follows:

§ 184.1979a Reduced lactose whey.

* * * * *

(b) * * *

(1) The analysis of reduced lactose whey, on a dry product basis, based on analytical methods in the referenced sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North

Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

17. Section 184.1979b is amended by revising the introductory text of paragraph (b)(1), by revising paragraph (b)(2), and by removing footnote number ''1'' to read as follows:

§ 184.1979b Reduced minerals whey.

* * * * *

(b) * * *

(1) The analysis of reduced minerals whey, on a dry product basis, based on analytical methods in the referenced sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for

Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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18. Section 184.1979c is amended by revising the introductory text of paragraph (b)(1), by revising paragraph (b)(2), and by removing footnote numbers ''1'' and ''2'' to read as follows:

§ 184.1979c Whey protein concentrate.

* * * * *

(b) * * *

(1) The analysis of whey protein concentrate, on a dry product basis, based on analytical methods in the referenced sections of ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th ed. (1980), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, is given in paragraphs (b)(1)(i) through (b)(1)(vii) of this section. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW.,

rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

(2) Limits of impurities are: Heavy metals (as lead). Not more than 10 parts per million (0.001 percent), as determined by the method described in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 760–761, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address ''http://www.nap.edu''), or may be examined at

the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

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Dated: 12/7/98

December 7, 1998

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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